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HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
BUDGET

United States Senate

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May 10, 2022

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10902 New Hampshire Ave
Silver Spring, MD 20993

The Honorable Tom Vilsack
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, D.C., 20250

Dear Commissioner Califf and Secretary Vilsack:

I write to ensure the federal government is taking every available step to get to the bottom of an increasingly urgent, nationwide shortage of infant formula, including the possible connection to several infant deaths. The responsibility falls on the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) to protect infant health by ensuring they have access to safe formula, and when crises arise, to initiate contingency plans to mitigate shortages that risk the lives of infants across the nation. Given the serious implications of the current shortage on infant health, I am deeply concerned about the apparent lack of an effective mitigation strategy and urge both agencies to move as fast as possible to safely resolve this situation.

Between the risk of ingesting contaminated formula, and the risk of malnutrition from an inability to receive said formula, the FDA is an exceedingly difficult position protecting infant health. I appreciate the FDA's efforts to support case-by-case release of essential product, but the pace of release is far slower than demand felt across our nation. In its attempt to balance safety from contaminated product and safe infant development through formula access, FDA is achieving neither objective. I, and millions of families across the nation, are eager to learn the status of your investigation into the powdered infant formula manufactured at Abbott Nutrition's Sturgis, Michigan facility, the impact of the voluntary recall on critical access for infants with special dietary needs, and the role of our federal agencies in infant formula oversight and access.

To date, there are four adverse events and tragically two deaths allegedly associated with Abbott Nutrition powdered infant formulas from this facility.[1] In both instances, *Cronobacter sakazakii* infection may have contributed to the cause of death, given that the bacteria were found in the facility during the course of a January 2022 – March 2022 inspection.[2] *Cronobacter* illnesses are rare but can be deadly for infants. According to the Centers for Disease Control and Prevention, the bacteria can spread at the production facility if contaminated raw materials are used to make formula or if the formula powder is in contact with a contaminated surface.[3] I am alarmed to see documented instances of non-descript contamination in September 24, 2021,[4] and inadequate sample testing to prove formula products met microbiological quality standards in 2019.[5] This documentation suggests FDA's routine inspection authority is insufficient to meet consumer safety demands, yet its hammer of near-shutdowns of facilities causes a ripple effect throughout the country.

[1] https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022
[2] https://www.fda.gov/media/157073/download
[3] https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html
[4] https://www.fda.gov/media/156747/download
[5] https://www.fda.gov/media/156748/download

In addition to the pressing urgency of investigating the cause of death and applying lessons learned to future Food and Drug Administration (FDA) inspections of infant formula manufacturers, we are extremely concerned about the formula product shortages affecting American families from the essential shutdown of the Sturgis facility. The recall and shutdown impacts affordability and availability of infant formula—several chain retailers are limiting the number of products per purchase to manage inventory and desperate families face skyrocketing costs through third-party sellers.[6] Infant formulas are also not easily interchangeable: some infants develop allergies or sensitivities, and some infants require specific formulas based on other medical conditions. It is essential FDA build in redundancies and robust supply chain analysis to prevent future life-threatening shortages.

Better understanding the authorities of FDA and USDA will help us more quickly address the current shortage and prevent future threats to infant health. We respectfully request your responses to the following questions:

1. Please describe in detail the cost/benefit analysis FDA undertakes to protect consumers from potentially contaminated products compared to a lack of product access?

2. Please provide a comprehensive update on the progress of the investigation, estimated timeline to completion, efforts to coordinate with other federal agencies, including the USDA, and any other authorities that may be necessary to help relieve the formula shortage.

3. Please describe in detail FDA's process for analyzing consumer complaints, including the amount of time, on average, it takes to review and investigate a complaint, the time it took to connect the three *Cronobacter sakazakii* complaints received by FDA, and the number of full-time equivalents that support FDA in this work.

4. FDA is not required on Form 483s to document every instance of questionable significance or other objectionable conditions.[7] During the September 20, 2021 – September 24, 2021 Sturgis Facility inspection, did FDA investigators find any other observations of questionable significance at the time of inspection that were excluded from the Form 483 report? If so, why were these observations excluded? Did FDA notify on-the-ground investigators of the first infant consumer complaint received on September 20, 2021 before the September 20, 2021 – September 24, 2021 inspection period concluded?

5. In the September 24, 2021 Form 483, observers noted on September 20, 2021, *"the Processing Operator did not sanitize nor change his gloves after touching non-food contact surfaces; immediately afterwards, he touched food contact surfaces including the inside of the potassium chloride ingredient bag [...]. In addition, the Operator's exposed wrists [...] were observed entering the inside of the potassium chloride ingredient bag when scooping ingredients."*[8]
    a. When FDA investigators identify clear instances of contamination, what immediate steps are taken to ensure products do not leave the facility?
    b. What steps were taken in this inspection to ensure the observed contaminated products did not leave the facility?
    c. It is my understanding FDA notifies company management immediately upon conclusion of the inspection to discuss the observations. Did that discussion take place following this inspection? If so, is it reasonable to conclude Abbott Nutrition had knowledge of

[6] https://www.nytimes.com/2022/05/08/business/baby-formula-shortage-retailers.html
[7] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions
[8] https://www.fda.gov/media/157073/download

contamination or potential contamination on or immediately following September 24, 2021?

6. Between September 24, 2021 and December 18, 2021, FDA received three additional consumer complaints. A follow-up facility inspection did not begin until January 31, 2022. Why did FDA take 44 days to initiate a follow-up inspection?

7. Section 412(c)(1) of the Federal Food, Drug, and Cosmetic Act requires companies manufacturing or distributing new infant formula to register with the FDA ninety days before marketing said formula.[9]
    a. On average, how many new infant formula submissions does FDA receive in one year?
    b. What percentage of new submissions come from companies that have preexisting infant formula product on the market? What percent of submissions come from new market entrants?
    c. To what extent does FDA analyze new and existing infant formula submissions to discern diversity in global sources of ingredients and nutritional profile (sole-source nutrition versus supplemental formula)?

8. The impact of the voluntary recall affects families of all income levels, though the pain is particularly acute for those who are supported by the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); For 23 states and the District of Columbia, Abbott Nutrition is the sole-source WIC contractor.
    a. Please describe the extent to which USDA is reevaluating its model of sole-source WIC contracting, including offering multi-source contract options or shorter contract terms.
    b. To what extent is the FDA working with Abbott Nutrition to transition the safe release of products on a case-by-case basis to sustained release, particularly for infants with certain metabolic and gastrointestinal conditions and allergies?

We respect and appreciate the difficult job your agencies have in overseeing the current infant formula crisis, but we also cannot afford to waste any time finding a solution. Please provide us with a response to this urgent request by May 24, 2022.

Sincerely,

Mitt Romney
U.S. Senator (R-UT)

cc: Ms. Cindy Long, Administrator, Food and Nutrition Science, USDA

[9] https://www.fda.gov/food/registration-food-facilities-and-other-submissions/infant-formula-registration-submissions